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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,061	11/27/2001	Max Schaldach	7163-32	3174

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EXAMINER	
THALER, MICHAEL H	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,061	SCHALDACH ET AL.	
	Examiner	Art Unit	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 21-52* is/are pending in the application.

4a) Of the above claim(s) *7,9-13,35-40 and 42-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,14-17,21-34,41,51 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 7, 9-13, 35-40 and 42-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 19, 2004.

Claims 2-6, 8, 21-34 and 41 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis for "the first wall portion".

Claims 1, 2, 5, 6, 25 and 30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Turi (5,556,414). Turi, in figures 1-7 discloses a stent 20 for a vessel (col. 1, lines 40-42) comprising a tubular body 26 for expansion from a first condition to a second condition (col. 8, lines 1-5) wherein in the first condition, the stent being configured such that a first part of the stent is disposed radially inwardly relative to a second part of the stent (The vein 26, prior to be compressed about catheter 72, has a diameter which is equal to or greater than the diameter of the body passageway into which it is inserted as indicated from col. 4, line 59 to col. 5, line

7. When the vein 26 is compressed about catheter 72, it collapses and forms folds 27 as indicated in col. 7, lines 21-26 since, unlike member 22, it is not split along its longitudinal axis. In other words, when member 22 collapses, it does not form folds since loops 62 and 64 can overlap to accommodate its reduction in diameter as indicated in col. 6, line 62 to col. 7, line 1. However, when vein 26 collapses, it has no similar loops 62 or 64 and therefore must form folds 27 in the circumferential direction to accommodate its reduction in diameter. One of these folds is the claimed first part of the stent.) and wherein in the second condition, at least a portion of the first part changes its position relative to the second part from its position in the first condition such that the at least portion of the first part is not disposed inwardly relative to the second part of the stent (when the vein unfolds into a cylindrical configuration), wherein the tubular body consists essentially of human or animal tissue 26 of adequate elasticity. Alternatively, it would have been obvious that the tissue 26 of the Turi stent 20 has adequate elasticity since it expands with the cylindrical member 22 and since veins are elastic to some extent. As to claims 6 and 30, Turi discloses hardening agent (the portion of the adhesive described in col. 5, lines 49-52 which hardens the adhesive as it cures or dries).

Claims 4, 8, 22, 23, 27, 29, 32, 34 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turi (5,556,414). As to claims 4, 22 and 23, Turi fails to disclose the tissue being genetically modified. However, it is old and well known in this art to genetically modify tissue in order to obtain favorable characteristics for it. It would have been obvious to genetically modify the Turi tissue so that it too would have this advantage. As to claims 8 and 41, Turi fails to disclose the hardening agent (the component of the adhesive) enclosed in microcapsules. However, it is old and well known in this art to enclose adhesive in microcapsules in order to obtain the advantage of easily deploying the adhesive on the surface. It would have been obvious to enclose the Turi adhesive in microcapsules so that it too would have this advantage. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03).

Claims 3, 21, 24, 26, 28, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turi (5,556,414) in view of Atala (2003/0208279). Turi fails to disclose the tissue being cartilage. However, Atala teaches that tissue on a stent should be cartilage (paragraph [0041]) apparently in order to make the stent biocompatible (paragraph [0013]). It would have

been obvious to make the Turi tissue cartilage so that it too would have this advantage.

Claims 14-17, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turi (5,556,414) in view of Berg et al. (5,680,873). As to claim 14, Turi discloses a catheter comprising a distal end region (the distal portion of the balloon catheter 41) and a holding device for holding the stent (the balloon on the balloon catheter 41). Turi fails to disclose a sheathing device provided with an application device for applying a medium which is capable of flow to a surface of the stent. However, Berg et al. teach that a guide catheter 22 should be used with a balloon catheter in order to obtain the advantage of guiding the balloon catheter through the vasculature as well as delivering fluids to the body (col. 1, lines 13-21). It would have been obvious to include a guide catheter with the Turi balloon catheter so that it too would have this advantage. Note that the Berg et al. guide catheter 22 (the claimed sheathing device) has an application device (the feed passage of guide catheter 22 through which dye passes as described in col. 7, lines 17-20) which is provided at the sheathing device for applying a medium which is capable of flow to a surface of the stent. For example, after stent implantation, the balloon catheter could be removed from the

guide catheter and die could be delivered through the guide catheter to the stent. As to claim 15, Berg et al. disclose an application opening (at the extreme distal end of guide catheter 22). As to claim 16, the Berg et al. sheathing device 22 has an anti-adhesion coating 40 while Turi discloses a layer of adhesive in col. 5, lines 7-8 and 48-57.

Applicant's arguments filed May 1, 2006 have been fully considered but they are not persuasive. Although the Turi stent 20 includes two components (tubular body 26 and member 50), the tubular body 26 itself consists essentially of human or animal tissue. Note the term "comprising" in claim 1, line 1 which does not limit the number of components of the stent. As to claims 6 and 30, it is the portion of the adhesive that hardens the adhesive as it cures or dries (and not the portion which is hardened) which is considered to meet the terms of this claim.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will

expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

mht
6/23/06

MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731